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Buelna et al.

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[45] **Date of Patent: Nov. 17, 1998**

[54] **WOUND CLOSURE APPARATUS AND METHOD**

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[73] Assignee: **C.R. Bard, Inc.**, Murray Hill, N.J.

[21] Appl. No.: **891,957**

[22] Filed: **Jul. 14, 1997**

Related U.S. Application Data

[63] Continuation of Ser. No. 502,482, Jul. 14, 1995, Pat. No. 5,700,273.

[51] **Int. Cl.**[6] **A61B 17/04**

[52] **U.S. Cl.** **606/148**; 606/144

[58] **Field of Search** 606/148, 144, 606/143, 145, 139, 233, 185; 128/898

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Primary Examiner—Michael Buiz
Assistant Examiner—Kevin Truong
Attorney, Agent, or Firm—Morgan & Finnegan, L.L.P.

[57] **ABSTRACT**

Apparatus for suturing a wound in a body cannula having an axis extending between a proximal end and a distal end. A handle is disposed at the proximal end and a pair of needles disposed at the distal end, the needles being movable between a proximal position and a distal position. A suture manipulator carried by the cannula is insertable through the wound and operable to manipulate the suture into an engaging relationship with the needles on the far side of the body wall. A finger tab is movable on the handle in a single distal direction through multiple stage. In a first stage the needles are deployed; in a second stage, the suture manipulator is activated to thread the needles; and in a third stage the suture is released from a tensioning mechanism. In an associated method the needles are threaded on the far side of the body wall and withdrawn from the wound providing access to the suture ends on the near side of the body wall. Tying the suture ends closes the wound.

11 Claims, 6 Drawing Sheets

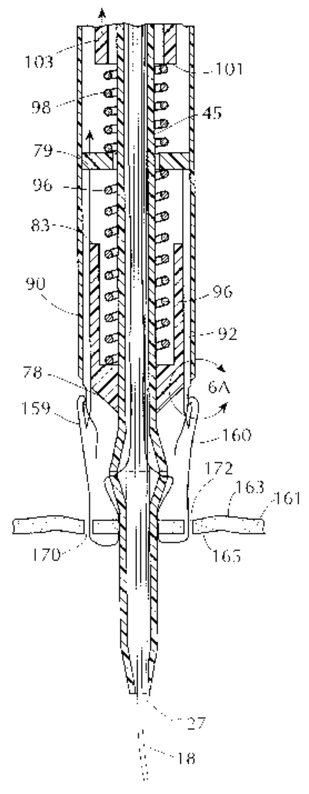

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FIG. 1

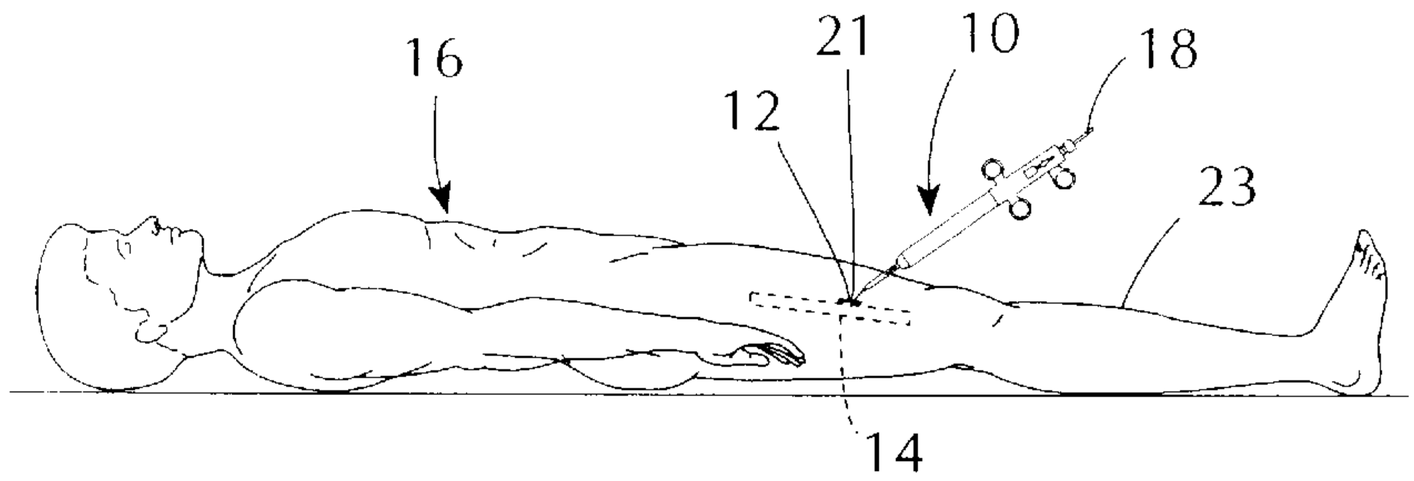


FIG. 2

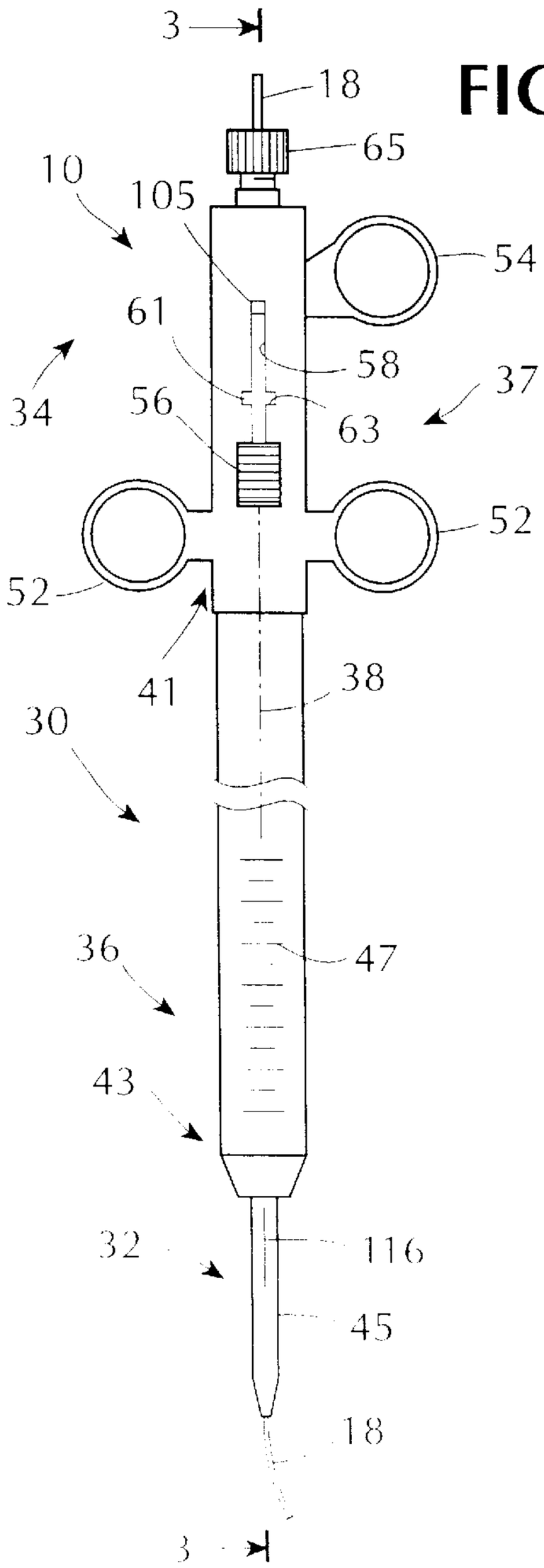


FIG. 3A

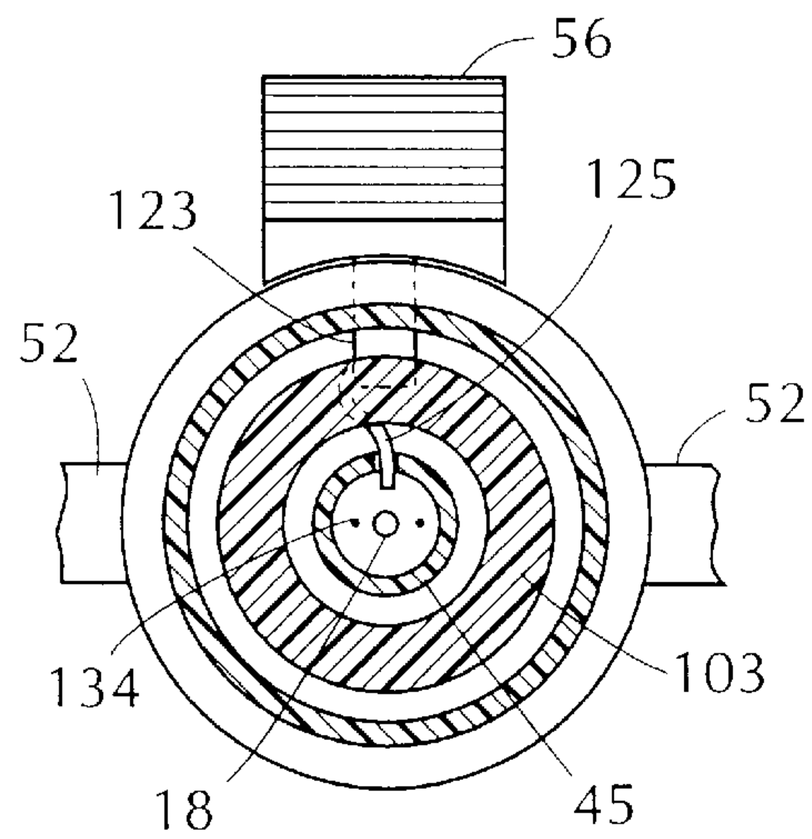


FIG. 3B

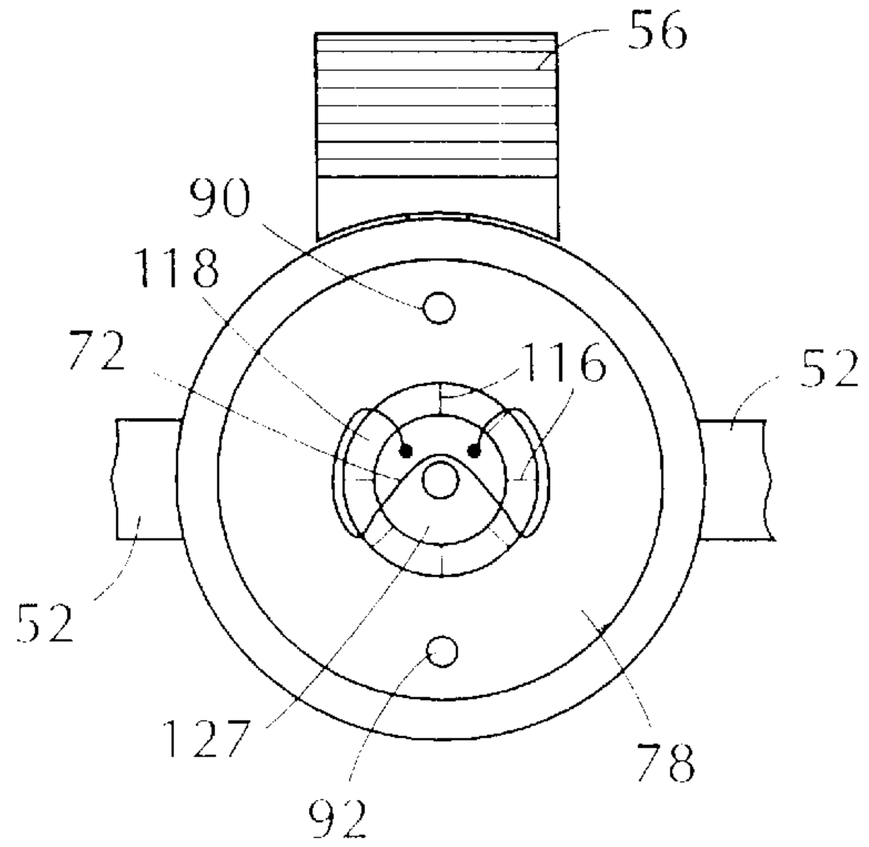


FIG. 3

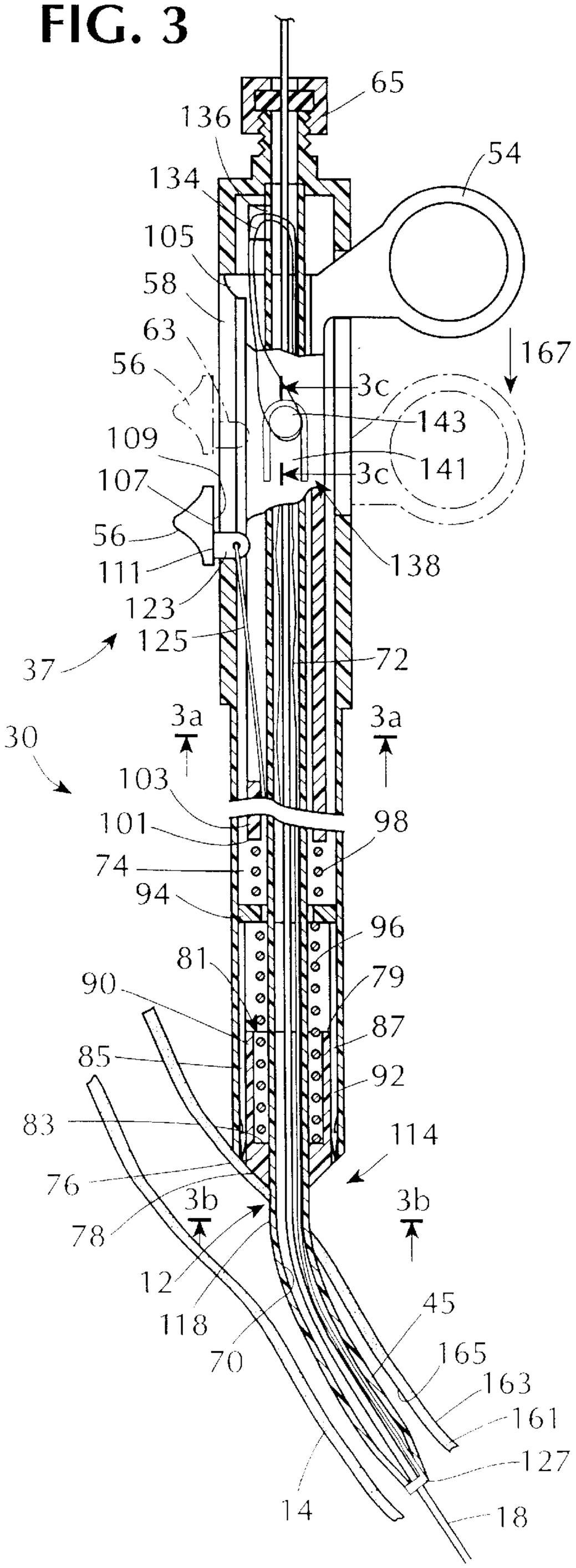

65
136
134
54
105
58
63
167
56
3c
143
109
141
3c
107
56
138
111
123
125
37
72
3a
3a
30
103
101
98
74
94
96
81
79
90
87
85
92
83
114
76
3b
3b
78
12
118
45
70
165
163
161
127
14
18

FIG. 4

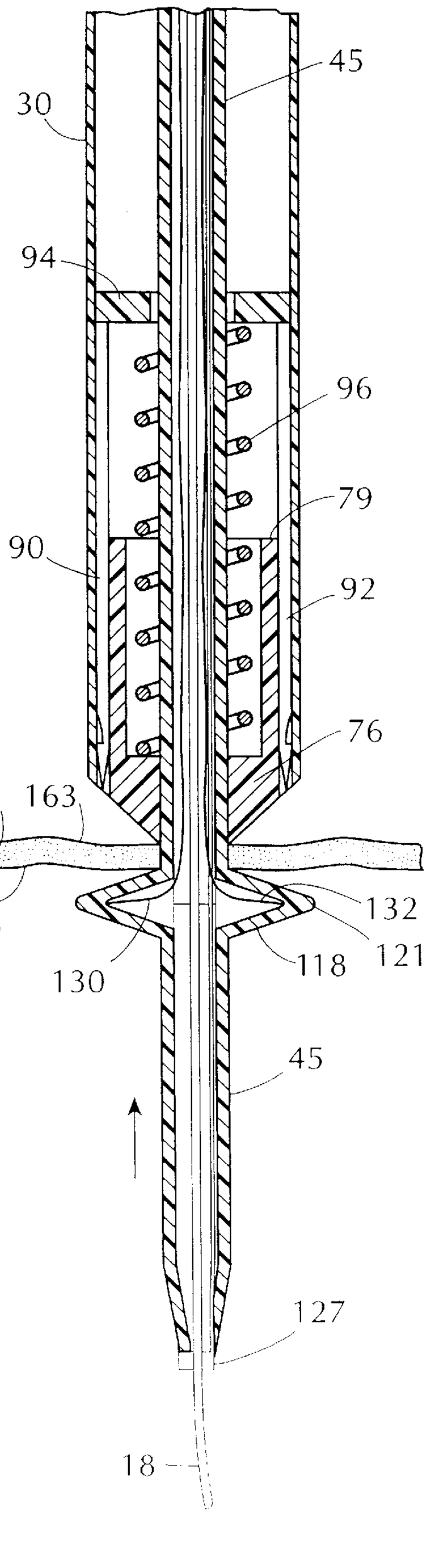

45
30
94
96
79
90
92
76
161
163
165
132
121
118
130
45
127
18

FIG. 9

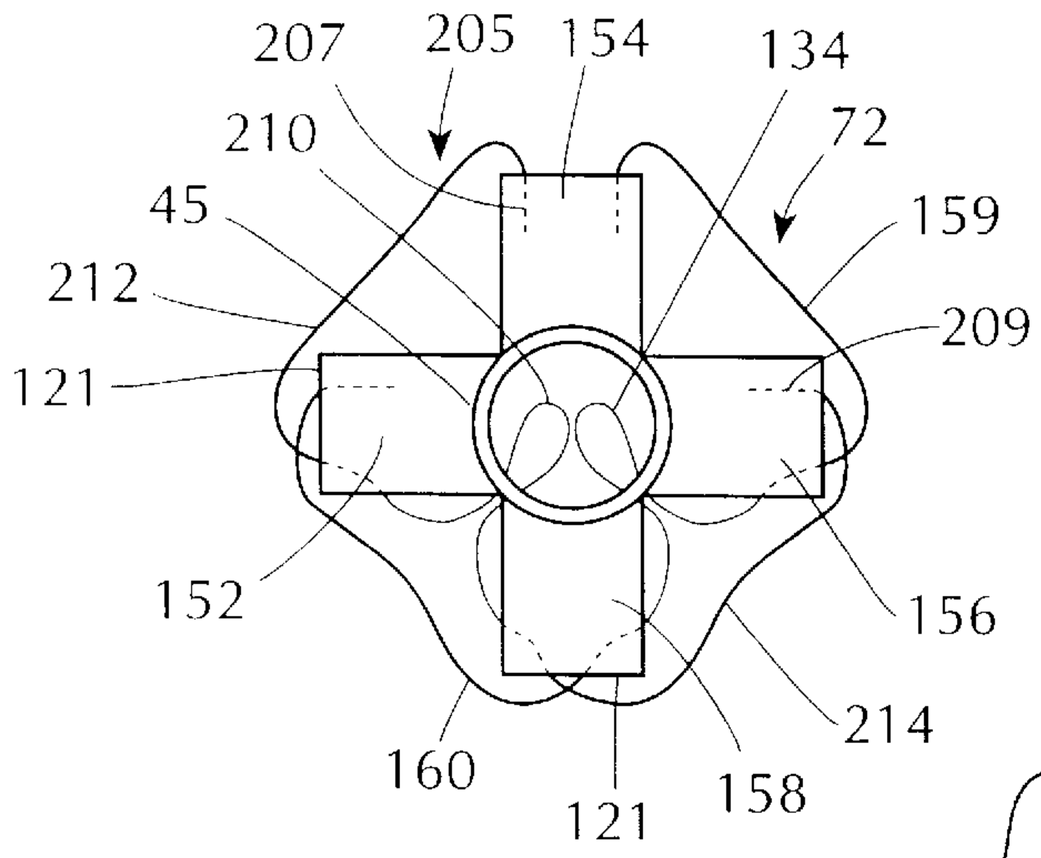


FIG. 10

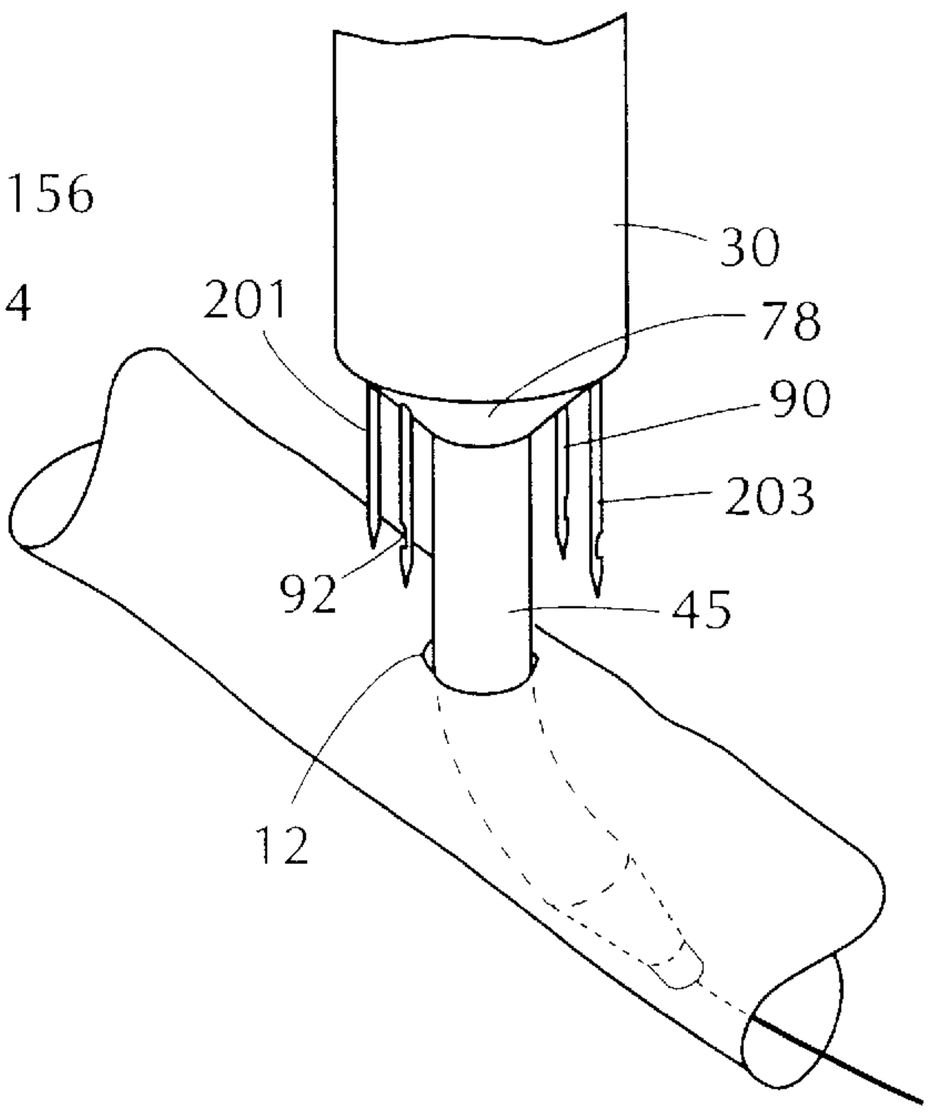
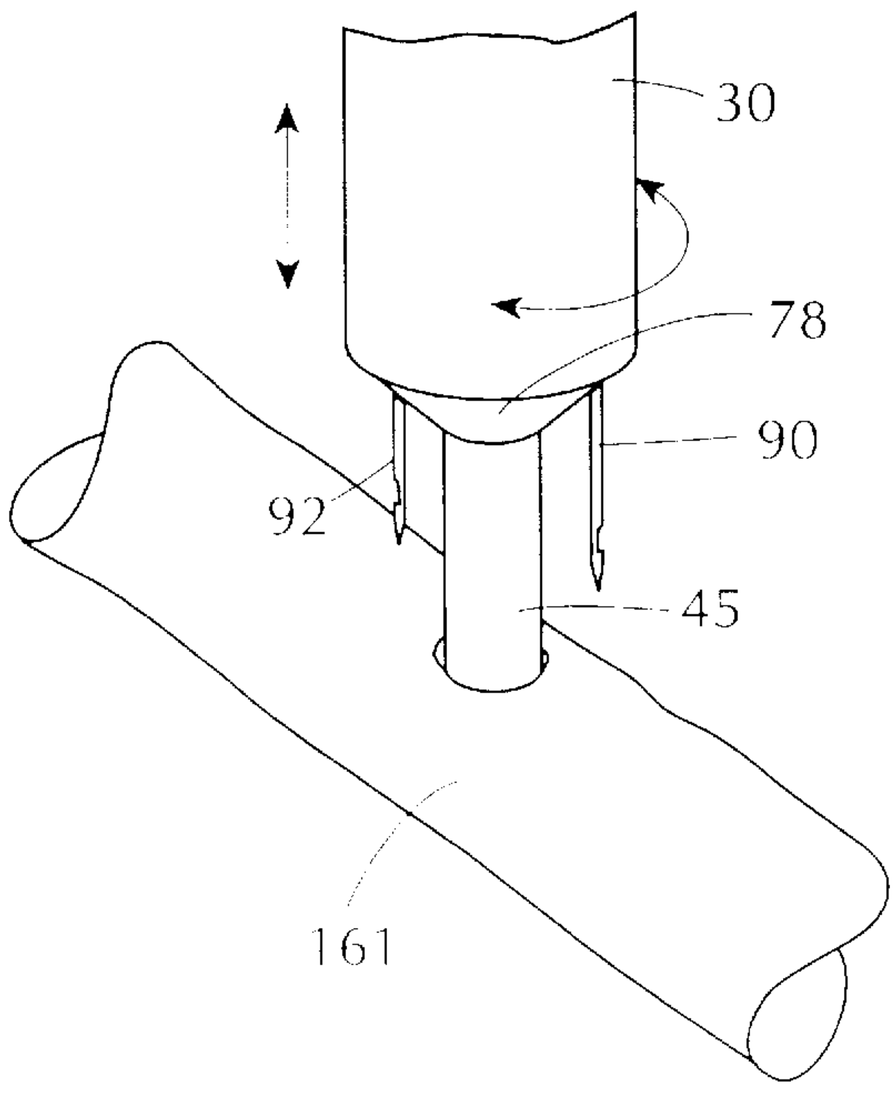


FIG. 11



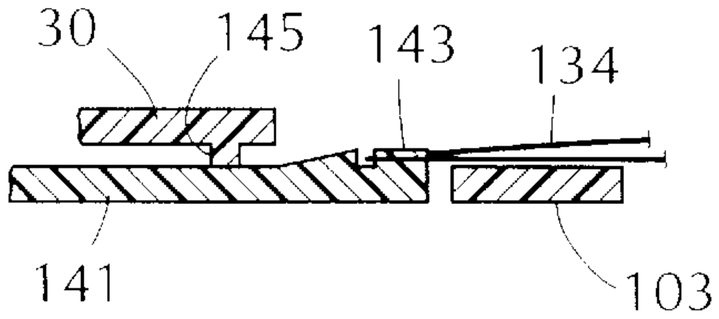


FIG. 3C

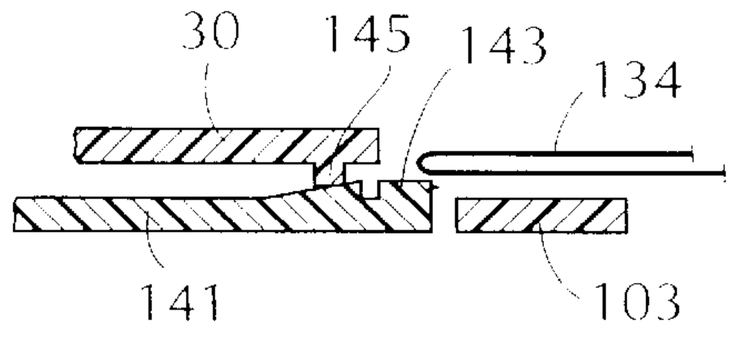


FIG. 3D

FIG. 5

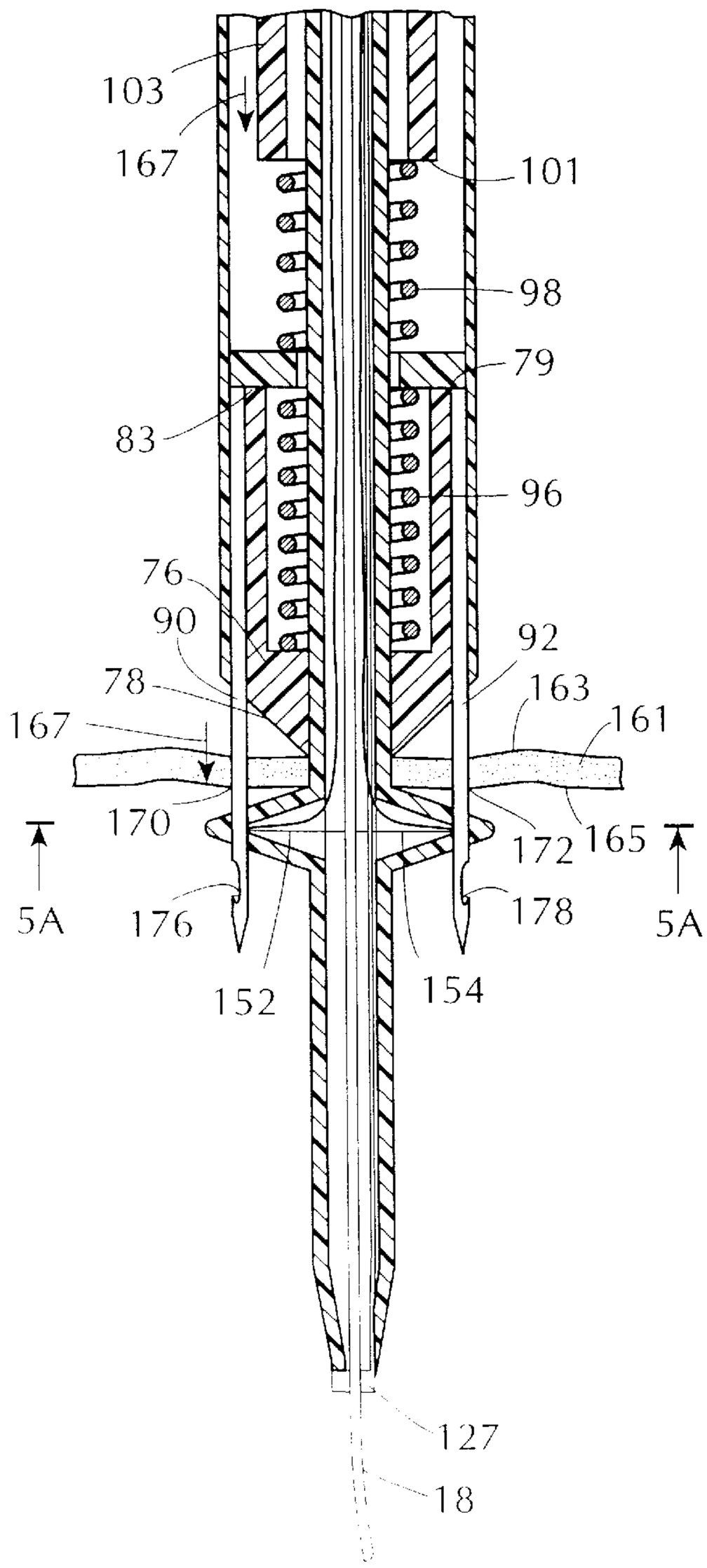
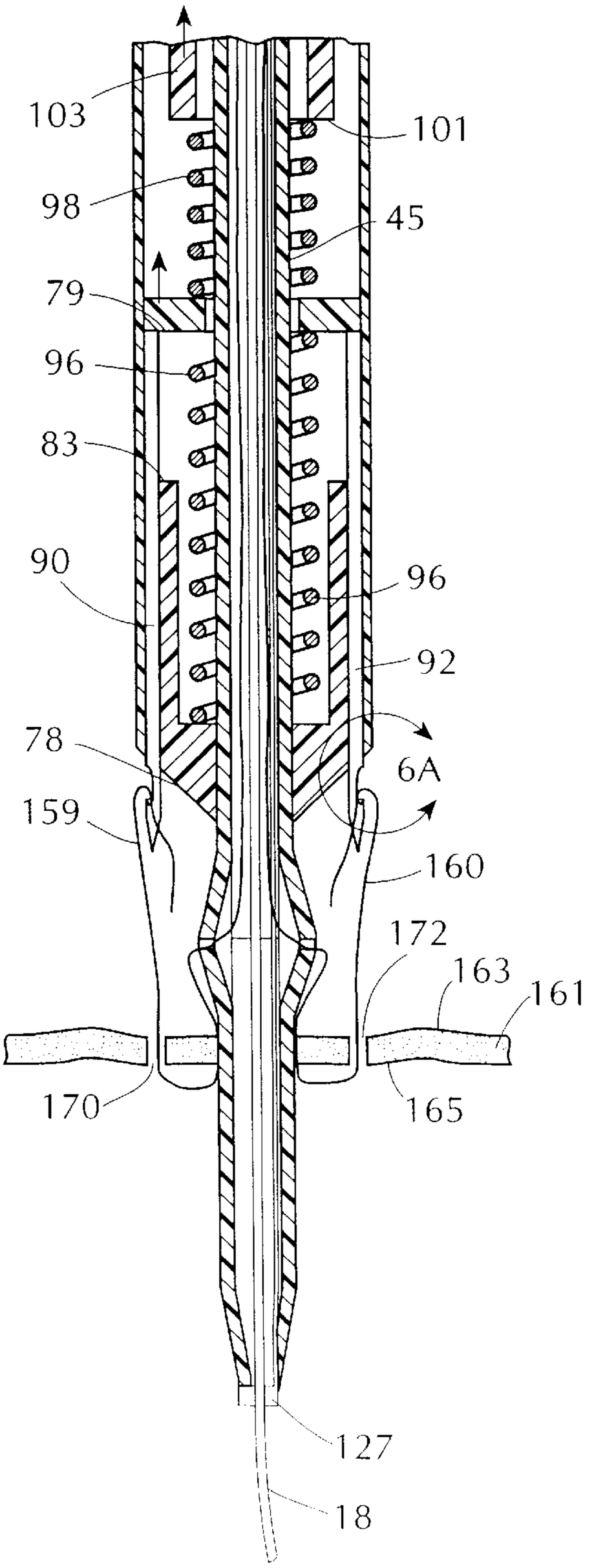

103
167
101
98
79
83
96
76
90
92
78
163
161
167
170
172
165
5A
5A
176
178
152
154
127
18

FIG. 6


103
101
98
45
79
96
83
90
96
92
78
6A
159
160
172
163
161
170
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127
18

FIG. 5A

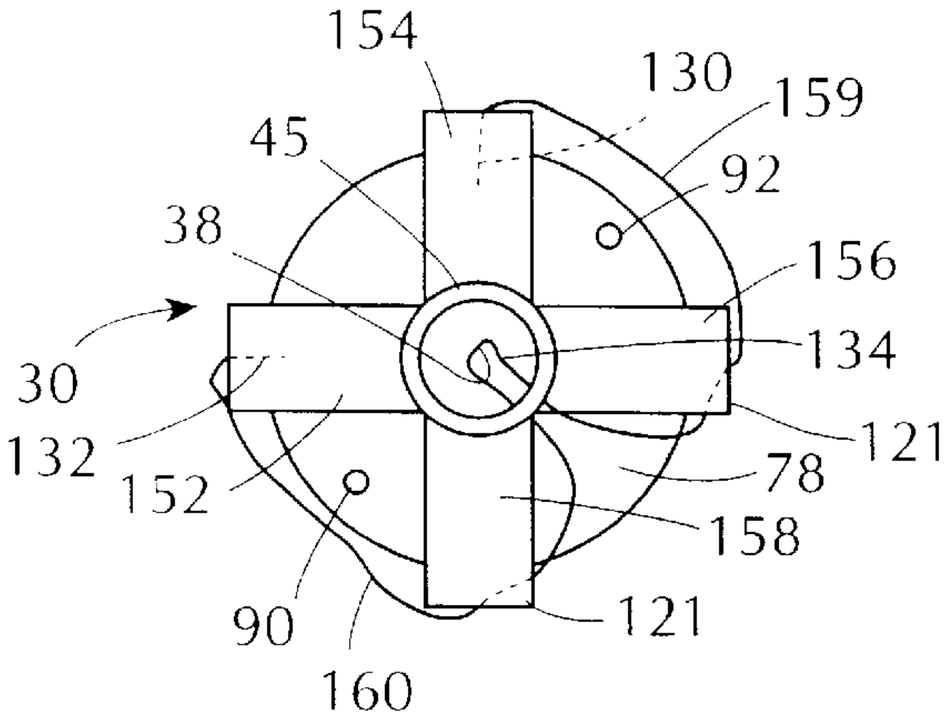


FIG. 5B

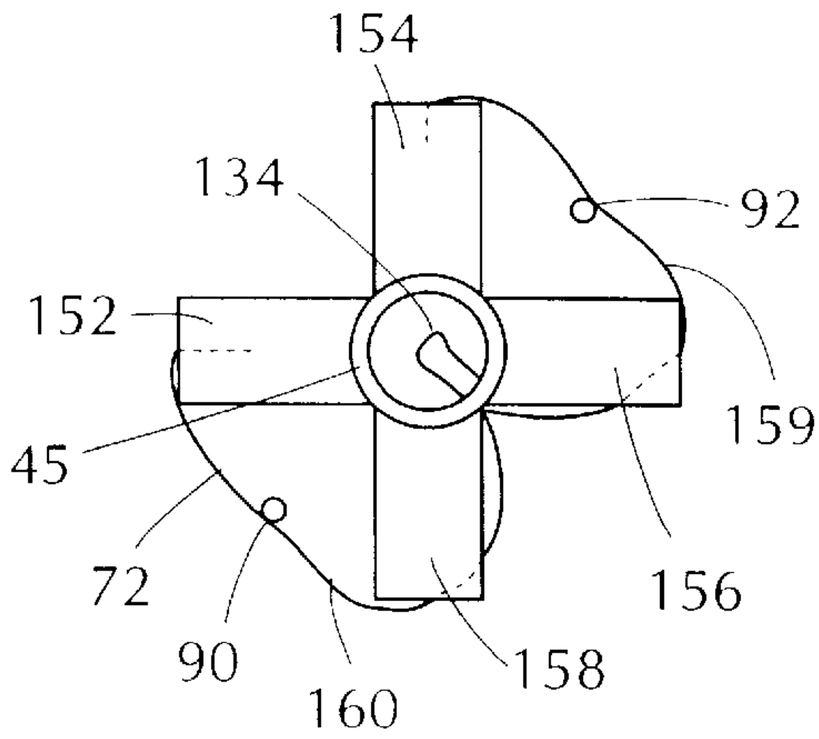


FIG. 6A

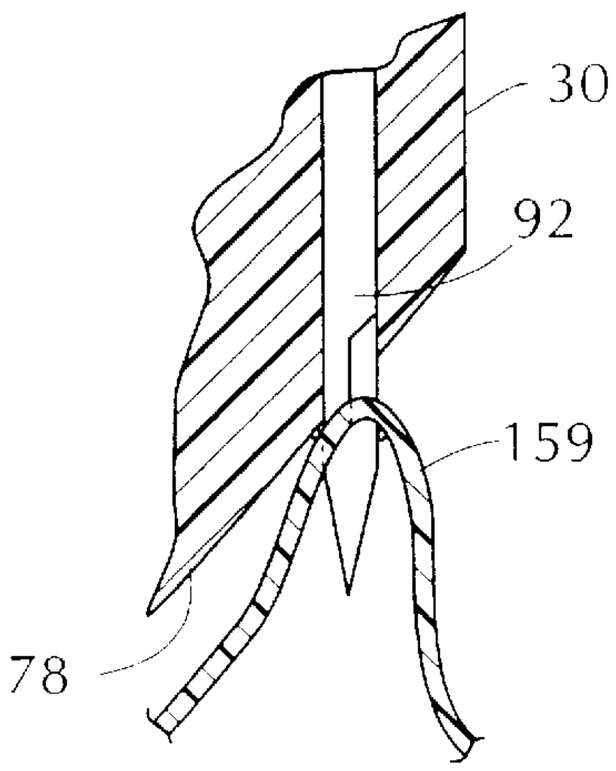


FIG. 7

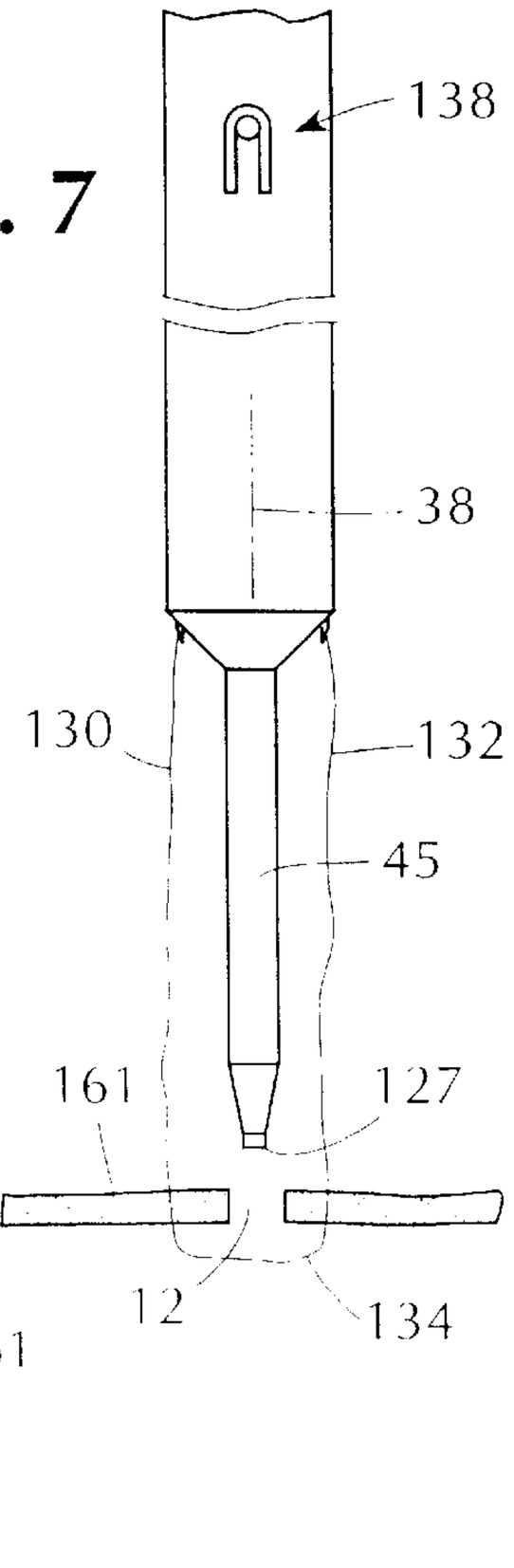


FIG. 8

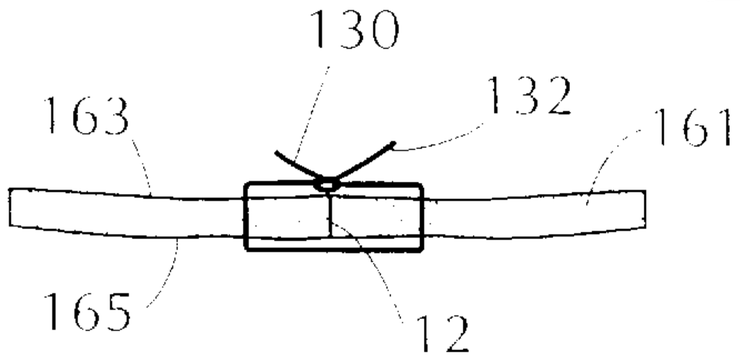
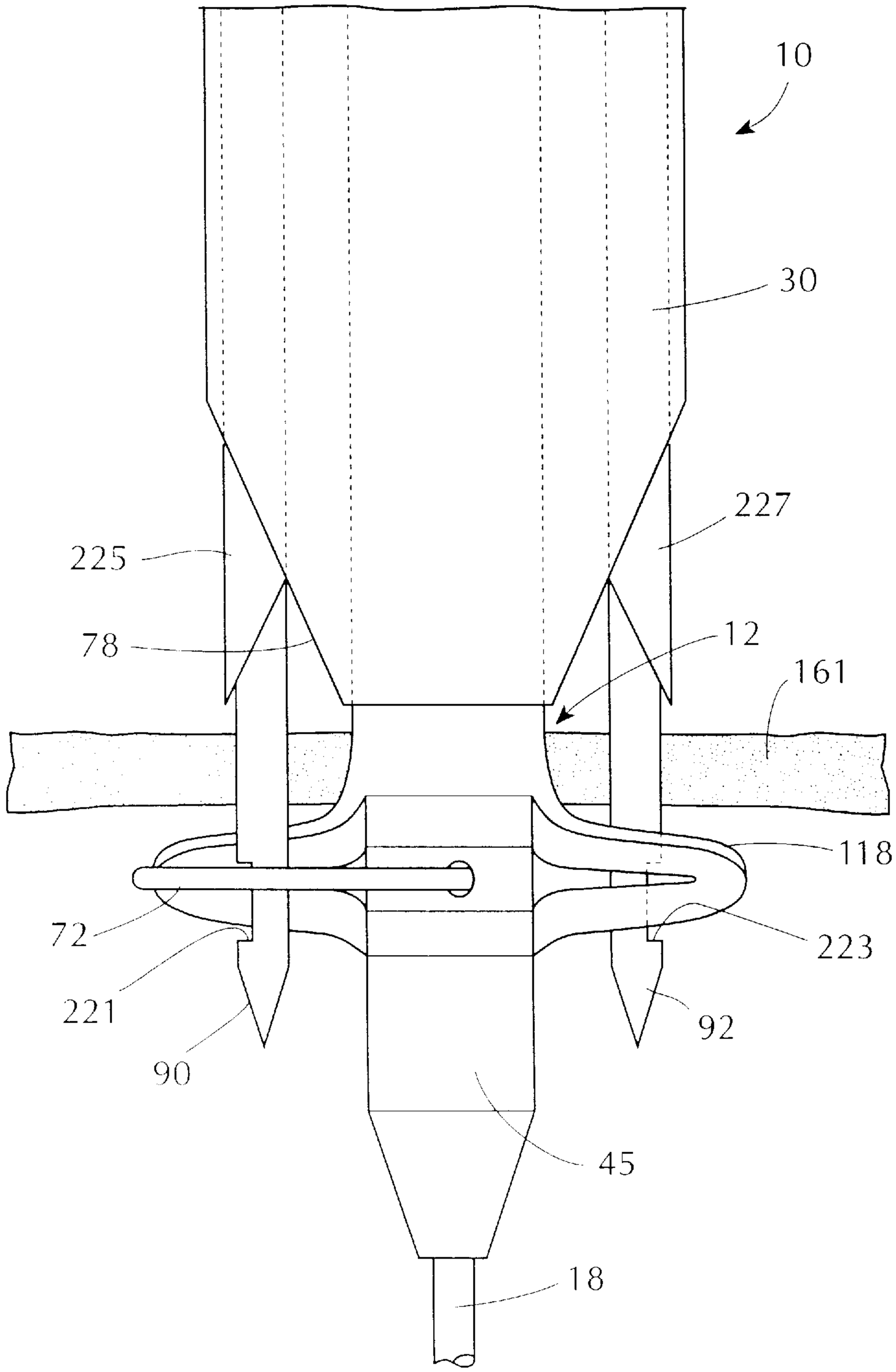


FIG. 12



WOUND CLOSURE APPARATUS AND METHOD

This is a continuation of application Ser. No. 08/502,482 filed Jul. 14, 1995 now U.S. Pat. No. 5,700,273.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to apparatus and methods for closing a wound or hole in a body wall, and more specifically to wound closure devices using suture material.

2. Discussion of the Prior Art

A puncture-type wound in a body wall can be created either unintentionally, or intentionally as part of a surgical procedure. In either case, the wound typically has the configuration of a hole extending through the body wall where access to the far side of the wall is available only through the wound.

The wound in the body wall may be accidentally created but it is more likely that it will be intentionally created in a surgical procedure associated with interventional cardiology, for example.

Surgical procedures involving interventional cardiology commonly produce a wound in the femoral or iliac artery of the patient. In this case, the body wall in which the wound is formed is the wall of the artery which is disposed some distance beneath the skin of the patient. When these arteries are punctured, wounds or holes are left in the tissue wall forming the arteries. Currently, large caliber access sheaths and dilators are used which merely accentuate the size of the wound and demand an appropriate suturing apparatus and technique for closing the wound. Wounds of this type have been addressed with direct hand pressure or specialized weights, bandages and dressings. These implements, requiring placement for extended supervised periods of time, also result in considerable discomfort to the patient. Other types of closure devices include bioresorbable plugs which in some cases provide a matrix which facilitates clotting. More recently, devices have been used which include needles and attached sutures which have been inserted into the vessel. The needles have been driven outwardly through the wall of the vessel where the suture ends have been captured and retrieved for knot tying.

Similar devices are represented by U.S. Pat. No. 5,417,699 which disclose a pair of proximally facing needles insertable through the wound and radially expandable so that upon retraction of the device the needles extend through holes in the surrounding tissue. The prethreaded holes are then drawn outwardly through the tissue wall along with the ends of attached sutures. This construction requires a special needle capture mechanism to pull the needles proximally through the body wall.

SUMMARY OF THE INVENTION

The wound closure device of the present invention includes a distal cannula which is insertable through the wound and functions to provide a suture on the far side of the body wall. A handle of the device remains on the near side of the body wall. A finger tab operable on the handle manipulates the suture on the far side of the body wall between radially spaced outer and inner positions. A needle deployment mechanism, also operable on the handle, deploys needles from a proximal position to a distal position. In the distal position, the needles extend through needle holes in the surrounding tissue of the body wall, and into

proximity with the suture on the far side of the body wall. In this position, the needles are disposed between the first and second positions of the suture so that manipulation of the suture between the first and second positions results in engaging the needle. The needles can then be withdrawn to capture the ends of the suture and to bring those ends through the needle holes to the near side of the body wall. At this point, the entire wound closure device can be retracted leaving the suture ends extending through tissue on opposite sides of the wound. Tying a knot between these ends tightens the suture across the wound to accomplish closure.

The apparatus for threading the needle on the far side of the body wall can include a Mallicot structure legs which is radially expandable and contractible to move the suture into threading engagement with the needles. This mechanism is operable from the handle of the apparatus on the near side of the body wall.

Apparatus for deploying the needles between the proximal and distal positions is also operable from the handle. This apparatus not only moves the needle but also trips the threading mechanism when the needles are appropriately positioned for threading. Further operation of the deployment mechanism frees the suture loop from a tensioning mechanism after the needles have been threaded, thereby permitting the apparatus to be withdrawn from the wound with the suture appropriately positioned to facilitate closure of the wound.

In one aspect of the invention, a wound closure apparatus is adapted for suturing a wound in a tissue wall. The apparatus includes a cannula having an axis extending between a proximal end and a distal end. A handle is disposed at the proximal end of the cannula. At least one pair of needles is disposed in proximity to the distal end of the cannula, the needle being movable between a proximal position and a distal position wherein the needle extends through the tissue wall. A suture manipulator carried by the cannula is insertable through the wound and operable to manipulate the suture into an engaging relationship with the needle when the needle is in the distal position.

An associated method results in suturing a wound formed in tissue of a body wall having a near side and a far side. Steps of the method include providing a suture having a first end, a second end, and a suture loop extending therebetween. The first and second ends of the suture are inserted through the wound leaving the suture loop on the near side of the body wall. Inserting an unthreaded first needle and an unthreaded second needle through the tissue places the distal ends of the needles on the far side of the body wall. The method also includes the steps of threading the first and second needles on the far side of the wall with respective ends of the suture, and withdrawing the threaded needles together with the associated first and second ends of the sutures to the near side of the body wall. Then the suture ends can be tensioned to draw the suture loop to the far side of the body wall, and tied to draw the tissue into proximity and thereby close the wound in the body wall.

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side elevation view of a patient and illustrating one embodiment of a wound closure apparatus of the present invention being used to close a wound in the femoral artery of the patient;

FIG. **2** is a front elevation view of one embodiment of the wound closure apparatus illustrated in FIG. **1**;

FIG. **3** is an axial cross section view of the apparatus taken along lines **3**—**3** of FIG. **2**;

FIG. **3**A is a radial cross section view taken along lines **3**A—**3**A of FIG. **3**;

FIG. **3**B is a radial cross section view taken along lines **3**B—**3**B of FIG. **3**;

FIG. **3**C is a cross-section view of a suture tensioning mechanism taken along lines **3**C—**3**C of FIG. **3**;

FIG. **3**D is a cross-section view of the suture tensioning mechanism illustrated in FIG. **3**C, the mechanism being deactivated to release the suture;

FIG. **4** is an axial cross section view similar to FIG. **3** and showing one embodiment of a suture deployment mechanism associated with the present invention;

FIG. **5** is an axial cross section view similar to FIG. **4** and showing one embodiment of a needle deployment mechanism associated with the present invention, the needle mechanism being illustrated in a distal position suitable for threading the needles;

FIG. **5**A is a radial cross-section view taken along lines **5**A—**5**A of FIG. **5**, and showing the suture deployment mechanism in an expanded state prior to threading;

FIG. **5**B is a radial cross-section view similar to FIG. **5**A and showing the suture deployment mechanism in a radially contracted state with the suture tightly held against the needles for threading;

FIG. **6** is an axial cross section view similar to FIG. **5** and showing the needles in a retracted position after being threaded;

FIG. **6**A is an enlarged view of the threaded needles in the retracted position illustrated in FIG. **6**;

FIG. **7** is a side elevation view illustrating the wound closure apparatus fully removed from the wound with the suture ends extending through the surrounding body wall;

FIG. **8** is a side elevation view of the suture ends tied to close the wound in the body wall;

FIG. **9** is an end view similar to FIG. **5**A and showing an alternate orientation of the suture to facilitate the threading of needles in an embodiment suitable for forming more than one pair of needle holes;

FIG. **10** is an elevation view of a further embodiment of the apparatus including two pairs of needles; and

FIG. **11** is an elevation view of the wound closure apparatus being rotated so that a single pair of needles creates more than one pair of needle holes.

FIG. **12** is a side elevation view of a further embodiment of a wound closure apparatus including a pair of suture capture needles.

DESCRIPTION OF PREFERRED EMBODIMENTS AND BEST MODE OF THE INVENTION

A wound closure apparatus is illustrated in FIG. **1** and designated generally by the reference numeral **10**. The apparatus **10** is illustrated in use for closing a wound **12** in a femoral artery **14** of a patient **16**. The wound **12** would typically have been intentionally created in order to provide access through the femoral artery **14** to the cardiovascular system of the patient **16**. In this case, the wound **12** is formed in the tissue of a body wall which forms the femoral artery **14**. Thus, portions of the femoral artery define the hole or wound **12** in the body wall. The apparatus **10** is typically introduced into the artery **14** over a guidewire **18** which extends through an incision **21** in the skin **23** of the patient **16**.

It will be understood that although FIG. **1** illustrates the suturing of a wound **12** interiorly of the skin **23**, the apparatus **10** is equally adapted for use in suturing a wound in any body wall including the skin **23**.

A preferred embodiment of the wound closure apparatus **10** is illustrated in FIG. **2** and consists generally of a cannula **30** having a distal section **32**, a proximal section **34**, and an intermediate section **36**. In this particular embodiment, the proximal section **34** comprises a handle **37**, the distal section comprises a flexible catheter **45**, and the intermediate section **36** comprises a generally rigid tube. The cannula **30** is otherwise defined by an axis **38** which extends between a proximal end **41** and a distal end **43** of the apparatus **10**.

The cannula **30** is generally hollow in order to facilitate insertion of the apparatus **10** over the guidewire **18** which is shown at both the proximal and distal ends **41** and **43** respectively. Graduations **47** can be provided on the exterior surface of the intermediate section **36** in order to measure the depth of the wound **12** relative to the skin **23**. Radiopaque marker rings can also be provided on the catheter **45** to facilitate fluoroscopic guidance and X-ray contrast.

The handle **37** includes a pair of stationary finger rings **52**, and an actuator in the form of an axially movable finger ring **54** which is discussed in greater detail below. A finger tab **56** is also movable along the handle **37**. This finger tab **56** rides within an elongate groove **58** which includes a slot **61** having a proximally facing shoulder **63**. The embodiment of FIG. **2** is also provided with a Touhy-Borst valve **65** which can be tightened to seal against the guidewire **18**. Back-bleeding through the catheter **45** can be evidenced through the Touhy-Borst valve **65** to provide a visual indication that the catheter **45** is located within the artery **14**.

The interior regions of the cannula **30** are illustrated in FIG. **3**. From this view it can be seen that the catheter **45** in this particular embodiment extends from the proximal end **41** and exits the cannula **30** through the distal end **43**. Thus the catheter **45** forms a hollow tube within the hollow tube of the cannula **30**. An inner channel **70** associated with the catheter **45** is adapted to receive not only the guidewire **18**, but also a suture **72** which is described in greater detail below. An inner channel **74** associated with the cannula **30** is provided with a plug **76** at its distal end **43**. This plug **76** has a distally facing outer surface **78**, a proximally facing shoulder **79**, and an annular recess **81** terminating within the channel **74** at a proximally facing surface **83**. Radially outwardly of the recess **81**, a pair of longitudinal needle bores **85**, **87** are provided which extend generally parallel to the axis **38** from the cannula channel **74** to the outer surface **78**.

A pair of needles **90**, **92** are mounted for reciprocal movement within the respective bores **85** and **87**. These needles **90**, **92** are carried by a common radial flange **94** which is disposed within the channel **74** of the cannula **30** but is suitably apertured to receive the catheter **45** along the axis **38**. On the distal side of the flange **94**, a needle return spring **96** is disposed to extend from the surface **83** of the recess **81** to the flange **94**. On the proximal side of the flange **94**, a travel slack spring **98** extends from the flange **94** to a distally facing surface **101** of an elongate cylinder **103**. This cylinder **103**, which is disposed coaxial with and interiorly of the cannula **30**, and is moveable by operation of the finger ring **54** within the channel **74** of the cannula **30**. The catheter **45** extends through the cylinder **103** so that the cylinder **103** occupies a generally cylindrical space between the catheter **45** and the cannula **30**.

In this embodiment of the wound closure apparatus **10**, the finger ring **54** and attached cylinder **103** together with the springs **96**, **98**, the needles **90**, **92** and associated flange **94**

function as a deployment mechanism to initially deploy and ultimately retract the needles **90**, **92**. As the finger ring **54** is moved distally, the surface **101** of the cylinder **103** presses against the spring **98** which in turn forces the flange **94** and attached needles **90**, **92** distally against the bias of the spring **96**. Thus, distal pressure on of the finger ring **54** moves the needles **90**, **92** from a proximal position best illustrated in FIG. **3** to a distal position best illustrated in FIG. **5**.

When the finger ring **54** is moved backwardly or proximally, the cylinder **103** withdraws from the spring **98** and the force of the compressed spring on the flange **94** causes the needles **90**, **92** to return from the distal position illustrated in FIG. **5** toward the proximal position illustrated in FIG. **3**. The combination of the cylinder **103** and finger ring **54** is also provided with a trip mechanism in the form of a tang **105** which rides within the groove **58** to engage a flange **107** on the finger tab **56**. This flange **107** has an inclined surface **109** and a distal facing shoulder **111**, discussed in greater detail below.

A suture deployment mechanism **114** can be formed as part of the catheter **45** in general proximity to the distal surface **78** associated with the cannula **30**.

In a preferred embodiment, this suture manipulating mechanism **114** is formed by a plurality of slits **116** (best shown in the radial cross section view of FIG. **3**B) which are spaced around the circumference of the catheter **45**. These slits **116** define a plurality of fingers **118** perhaps best shown in FIG. **5**A. Each of the fingers **118** can be provided with an intermediated living hinge **121** which facilitates radial expansion of the fingers **118** when the catheter **45** is axially compressed. This radial expansion occurs between a first position illustrated in FIG. **3**, where the fingers **118** have a relatively low profile, to a second position illustrated in FIG. **4**, where the fingers **118** have a relatively high radial profile. In combination, the expandable fingers **118** form a device commonly referred to as a Mallicot structure. Between the first, low profile position and the second, high profile position of the fingers **118**, there exists a natural position described below with reference to FIG. **6**.

The suture manipulating mechanism **114** also includes the finger tab **56** and a projection **123** which extends from the tab **56** through the groove **58** and into the channel **74** of the cannula **30**. An elongate element **125** is fixed at its proximal end to the a projection **123** and at its distal end to a flange **127** at the distal tip of the apparatus **10**. This flange **127**, which is apertured to receive the guidewire **18**, is at least as large as the catheter **45** at the distal end **43** of the apparatus **10**. It is the purpose of the finger tab **56**, the element **125** and the flange **127** to move the fingers **118** between the low profile position and the high profile position. As the finger tab **56** is moved proximally, from the solid line position to the dotted line position in FIG. **3**, the element **125** is tensioned thereby drawing the distal flange **127** proximally. This creates an axial compression force on the catheter **45** which causes each of the fingers **118** to buckle at its ends and at the associated living hinge **21** thereby resulting in expansion of the finger **118** forming the Mallicot structure.

These fingers **118** can be maintained in the second, expanded position automatically by ensuring that the flange **107** associated with the finger tab **56** is appropriately lodged within the slot **61** associated with the groove **58**. Thus, the finger tab **56** can be locked in the proximal, dotted position when the flange **107** falls into the slot **61** and the distally facing surface **111** of the flange **107** engages the proximally facing surface **63** of the slot **61**. The resulting lock, which holds the tab **56** in its proximal position and holds the fingers **118** in their second expanded state, is released in a preferred embodiment when the tab **105** associated with the finger ring **54** and cylinder **103** engages the flange **107** forcing it out of the slot **61**. When the lock is released, it is the natural tendency of the fingers **118** to move back toward the low profile state. This forces the distal flange **127** distally tensioning the element **125** and drawing the finger tab **56** distally, from the dotted position to the solid line position in FIG. **3**. Distal finger pressure on the tab **56** can also facilitate movement of the fingers **118** from the high profile state toward the low profile state if the elongate element **125** can accommodate a compressive load.

This operation of the suture manipulating mechanism **114** and the expandable fingers **118** make this structure particularly useful in deploying the suture **72**. As best illustrated in FIGS. **3** and **4**, the suture **72** includes free ends **130** and **132** which can be embedded in or near the living hinge **121** of adjacent fingers **118**. Between the ends **130** and **132**, the suture forms a suture loop **134** which is relatively long and extends from the fingers **118** into the channel **70** of the catheter **45** and along substantially the entire length of the cannula **30** where it exits the catheter **45** through a pathway or hole **136**.

Exteriorly of the catheter **45**, the suture loop **134** engages a suture tensioning device **138** in the form of a tab **141** formed in the wall of the cylinder **103**. This tab **141** includes a post **143** which extends radially outwardly to receive the suture loop **134**. The tab **141** is compressible radially inwardly by a projection **145** on the inner surface of the handle **37**. As the cylinder **103** moves axially, by operation of the finger ring **54**, the projection **145** engages the tab **141** and moves it radially inwardly. This causes the suture **72** to clear the post **143** effectively dislodging the suture loop **134** from the tensioning device **138**. This feature is particularly advantageous during operation of the apparatus **10** for reasons discussed in greater detail below.

A preferred method for attaching the suture **72** to the fingers **118** can be best understood with reference to FIG. **5**A. In this embodiment, the fingers **118** are further designated by the reference numerals **152**, **154**, **156**, and **158**. In the view of FIG. **5**A, the fingers **152–158** are fully extended in the second position. The associated living hinges **121** are disposed at the bends of the fingers **152–158** where the fingers reach their maximum radial distance from the axis **38**.

With such an embodiment, the suture end **130** can be loosely embedded in the finger **154**, the suture can then be led from the finger **154** and through a slit in the living hinge **121** associated with the finger **156**. From this point, the suture loop **134** can be fed into the catheter **45** and along the length of the cannula **30**. In a similar manner, the suture end **132** can be loosely embedded in the finger **152** and led through a slit in the living hinge **121** associated with the leg **158**. With this orientation, each of the suture ends **130**, **132** forms a short section of suture which extends between adjacent legs. Thus, the suture end **130** extends between adjacent legs **154**, **156** to form a suture portion **159**, while the suture end **132** extends between opposing adjacent legs **152**, **158** to form a suture portion **160**.

Loading of the wound closure apparatus **10** can be accomplished during the final stage of manufacture. The finger tab **56** on the handle **37** is initially set to the distal position illustrated by the solid lines in FIG. **3**. This ensures that the fingers **118** forming the Mallicot structure are in the low profile state. The suture **72** can then be mounted on the fingers **118** and the suture loop **134** and threaded through the

channel **70** of the catheter **45**. After exiting the hole **136** in the catheter **45**, the suture loop **134** is disposed around the post **143** in the suture tensioner **138**. Finally, the movable finger ring **54** is placed in its proximal position so that the needles **90**, **92** are retracted into the associated bores **85**, **87**. The Touhy-Borst valve **65** can also be to loosened to allow insertion over the guidewire **18**.

Operation of the wound closure apparatus is begun by inserting the catheter **45** into the wound **12**. If the wound **12** is in the skin **23** of the patient **16**, the catheter **45** is introduced directly into the wound **12**. If however, as illustrated in FIG. **1**, the wound occurs in a body wall, such as the wall of the femoral artery **14**, the small incision **21** can be made in the skin **23** in order to gain access to the artery **14**. The guidewire **18** will typically have been placed through the incision **21** and wound **12** as part of the surgical procedure which developed the wound **12**.

With the guidewire **18** in place, the apparatus **10** can be positioned over the guidewire **18** so that the distal tip of the catheter **45** follows the guidewire through the incision **21** and the wound **12** into the artery **14**. At this point, the graduations **47** on the cannula **30** will provide an indication of the depth of the artery **14** relative to the skin **23**. Radiopaque markers on the catheter **45** can be useful to facilitate fluoroscopic guidance to an operative position. The Touhy-Borst valve **65** also provides a visual indication of backbleeding which would evidence proper placement within a blood vessel. The valve **65** can also be provided with a T-fitting to facilitate injections of X-ray contrast media through the catheter **45**.

With reference to FIG. **3**, it will be noted that the body wall, in this case a body wall **161** of the artery **14**, has a near side **163** and a far side **165**. Since access to the far side **165** of the body wall **161** is severely limited, it is of particular advantage to the present invention that wound closure can be achieved without direct access to the far side **165** except through the wound **12**.

In the preferred method, the catheter **45** is inserted through the wound **12** a distance sufficient that the fingers **118** forming a Mallicot structure are positioned on the far side **165** of the body wall **161**. The cannula **30** including the needles **90** and **92**, remain on the near side **163** of the body wall **161**. With this orientation, it will be noted that the suture ends **130**, **132** illustrated in FIG. **4** are positioned on the far side **165** while the suture loop **134** is positioned on the near side **163** of the body wall **161**.

This preferred operative position for the apparatus **10** is achieved by operation of the handle **37** and associated stationary rings **52**. With the apparatus **10** thus disposed, the fingers can be expanded from their first low profile state illustrated in FIG. **3** to their second expanded state illustrated in FIG. **4**. Note that this expansion of the fingers **118** results in the radial outward movement of the suture portion **159**, **160**.

With the suture portions **159**, **160** appropriately positioned, the needles **90**, **92** can now be deployed. These needles **90**, **92** are initially disposed in their associated bores **85**, **87** on the near side **163** of the body wall **161**. Deployment of the needles **90**, **92** is accomplished by moving the finger ring **54** and associated cylinder **103** distally in the direction of an arrow **167** in FIG. **5**. The distally facing surface **101** of the cylinder **103** compresses the spring **98** which in turn exerts a force on the needle flange **94**. This force, which is increased with further distal movement of the finger ring **54** against the bias of the spring **96**, moves the needles **90**, **92** beyond the distal surface **78** and through needle holes **170** and **172** respectively, in the body wall **161**. Distal movement of the needles **90**, **92** ceases when the flange **94** bottoms out on the proximal facing surface **79** of the plug **76**.

The needles **90**, **92** each have a needle eye **176**, **178** respectively, which in a preferred embodiment is in the form of a French eye. When the needles **90**, **92** are fully extended, these eyes **176**, **178** are preferably disposed on the far side **165** of the body wall **161** and beyond the suture portions **152**, **154**. With the suture portions **159**, **160** in their radially extended position, the needles **90**, **92** in their distal-most position, and the needle eyes **176**, **178** facing the suture portions **152**, **154**, the suture **72** can now be manipulated to thread the needles **90**, **92**.

In a preferred embodiment, this manipulation of the suture **72** is accomplished by further distal movement of the finger ring **54** to a second position where the tang **105**, riding within the groove **58**, engages the inclined surface **109** of the flange **107**. This engagement of the flange **107** by the tang **105** releases the finger tab **56** from its locked proximal position. This relieves tension on the element **125** and enables the fingers **118** to radially compress naturally as the catheter **45** elongates. The radial compression of the fingers **118** moves the suture portions **159**, **160** against the associated needles **90**, **92** at a position proximal to the eyes **176**, **178**.

Of course with the radial compression of the fingers **118**, the distance between the adjacent living hinges **121** is reduced. This would normally cause the suture portions **152**, **154** to become slack were it not for the suture tensioning mechanism **138** previously discussed. It will be noted that as the finger ring **54** is moved distally, the suture tensioning mechanism also moves distally. Since the hole **136** in the catheter **45** is disposed proximally of the tensioning mechanism **138**, the distal movement of the mechanism **138** creates proximal movement of the suture loop through the catheter channel **70**. This in turn tensions the suture portions **152** and **154** even as the fingers **118** are radially contracting.

To this point, distal movement of the finger ring **54** has operated to deploy the needles **90**, **92** in a first position, and to manipulate the fingers **118** in order to thread the needles in a second position of the finger ring **54**. This manipulation of the fingers **118** in the second position is accomplished while tensioning the sutures **72** with the mechanism **138**.

Further distal movement of the finger ring **54** to a third position results in removal of the suture loop **134** from the post **143** of the tensioner **138**. This has the effect of releasing the suture loop **134** from the apparatus **10** so that it is free to be drawn into the wound **12**. This freeing of the suture loop **134** is accomplished as illustrated in FIG. **3**B when distal movement of the cylinder **103** brings the tab **141** into proximity with the projection **145** on the handle **37**. This interfering relationship causes the tab **141** to compress radially inwardly thus forcing the suture loop **134** from the post **143** as illustrated in FIG. **3**D.

It will be noted at this point that movement of the finger ring **54** in a common distal direction operates to perform three sequential steps in a method for operating the apparatus **10**. In a first step associated with first distal position of the ring **54**, the needles **90**, **92** are deployed to a position where they can be threaded. In a second step associated with a second position of the ring **54**, the finger tab **56** is released thereby permitting contraction of the fingers **118** to facilitate threading the needles **90**, **92**. In a third step associated with a third position of the finger ring **54**, the suture loop **134** is released from the tensioning mechanism **138** to facilitate withdrawal of the apparatus **10**.

With the suture portions **152**, **154** tensioned radially against the needles **90**, **92** proximally of the eyes **176**, **178**, the needles **90**,**92** can now be retracted. Initially this retraction of the needles **90**, **92** causes the tensioned suture portions **159**, **160** to enter the eyes **176**, **178**. Further retraction of the needles **90**, **92** withdraws the captured suture portions **159**, **160** through the associated needle holes **170**, **172** in the skin **23**. At this point, both of the suture ends **130**, **132**, as well as the suture loop **134**, are disposed on the near side **163** of the wall **161**. The apparatus **10** can now be withdrawn from the wound **12**.

The needles **90**, **92** are preferably retracted until the eyes **176**, **178** enlarged by the presence of the suture portions **152**, **154** are biased against the distal surface **78** at the distal end of the cannula **30**. In this position of the needles **90**, **92**, illustrated in the enlarged view of FIG. **6**A, the suture ends **130**, **132** are trapped between the respective needles **90**, **92** and the cannula **30** due to return spring force.

With the suture loop **134** released from the post **143** of the tensioner **138**, removal of the apparatus **10** will draw the suture portions **159**, **160** further away from the body wall **161** as illustrated in FIG. **7**. This causes the suture loop **134** to be drawn distally through the catheter **45** until it exits from between adjacent legs **156**, **158** and is drawn through the wound **12** to the far side **165** of the body wall **161**.

Once the wound closure apparatus **10** has been fully removed from the wound **12**, the suture ends **130**, **132** can be removed or cut from the fingers **118** and tied with a surgeon's knot in a conventional manner. Such a knot can be pushed through the incision **21** and into proximity with the wound **12** as illustrated in FIG. **8**.

An additional embodiment of the invention is illustrated in FIG. **10** and includes two needle pairs. The needles **90** and **92** previously discussed form one of the needle pairs while an additional needle pair comprises needles **201** and **203**. In this case, the four needles **90**, **92**, **201** and **203** are displaced 90° from each other around the distal surface **78** of the cannula **30**. The needle deployment (not shown in FIG. **10**) can be similar to that previously discussed where the four needles **90**, **92**, **201** and **203** are fixed to the common flange **94** (best illustrated in FIG. **4**).

This embodiment of the invention functions to simultaneously apply two sutures to the wound **12**. The first suture can be that previously referenced with the numeral **72**. This suture can be laced to the suture manipulating mechanism illustrated in FIG. **9** in the same manner as discussed with reference to FIG. **5**. A second color-coded suture **205** can also be laced on to the legs **152**–**158** of the Mallicot structure in the manner illustrated in FIG. **9**.

This suture **205** having a first end **207** and a second end **209** is also characterized by a suture loop portion **210**. In a preferred method, the end **207** of the suture **205** is loosely held in the leg **154** of the Mallicot structure. The suture is then laced through the living hinge **121** and the leg **152** with the suture loop **210** extending into the channel associated with the catheter **45**. As the suture loop exits this channel, it can be passed through the living hinge **121** associated with the leg **158**. Finally, the end **209** of the second suture **205** can be loosely embedded in the leg **156**.

This configuration for the second suture **205** produces a suture portion **212** between the legs **152** and **154** and a second suture portion **214** between the legs **156** and **158**. In this manner, the two sutures **72** and **205** can form the four suture portions **159**, **160**, **212** and **214** for the respective needles **90**, **92**, **201** and **203**. The resulting suture deployment mechanism can be operated in the manner previously discussed to thread each of the four needles associated with the embodiment of FIG. **10**.

The dual suture embodiment of the suture deployment mechanism illustrated in FIG. **9**, can also be used with the two needle embodiment of the apparatus **10** previously discussed. In a preferred method of operation, the two needles **90**–**92** can be operated in the manner previously discussed to capture the suture portions **159** and **160**. Then the cannula **30** and needles **90**, **92** can be rotated 90° to function with respect to the suture portions **212** and **214**. Of course in this embodiment, means must be provided for rotating the cannula **30**, and needles **90**, **92** relative to the legs **152**–**158** forming the Mallicot structure.

FIG. **12** illustrates a further embodiment of the wound closure apparatus **10**. This embodiment includes the cannula **30** and catheter **45**, as well as the fingers **118** and associated suture **72**. The illustrated embodiment also includes the needles **90**, **92**, but in this case, the needle eyes (previously designated by the reference numerals **176**, **178**) are not formed as French eyes, but rather as mere slots **221**, **223**. As compared to the French eyes previously discussed, the slots **221**, **223** can be formed with a significantly lesser depth. As a result, the needles **90**, **92** can provided with a much smaller diameter.

The embodiment of FIG. **12** provides for effective suture capture with the provision of suture capture needles **225** and **227**. These needles **225** and **227** can be provided with a tubular configuration and a telescoping relationship with the associated needles **90**, **92**. The distal ends of the suture capture needles **225**, **227** can be sharpened to facilitate their deployment through the body wall **17**.

Operation of the FIG. **12** embodiment proceeds in the manner previously discussed with the needles **90**, **92** being deployed through the body wall **17**. With the more narrow configuration of the needles **90**, **92**, this step of deploying the needles should be more easily accomplished than in the FIG. **5** embodiment. As the suture **72** is manipulated by the fingers **118** in the manner previously discussed, the suture **72** is drawn into the slots **221**, **223** of the respective needles **90**, **92**. At this point, the suture capture needles **225**, **227** can be deployed by moving them distally along the associated needles **90**, **92**. As the distal end of the capture needles **225**, **227** approach the slots **221**, **223**, the suture **72** is pinched between the associated needles **90**, **225** and **92**, **227**.

With the suture **72** appropriately captured in the slots **221**, **223**, the needles **90**, **92** and associated capture needles **225**, **227** can be withdrawn toward the cannula **30**. Preferably after the needles **90**, **92** and **225**, **227** have cleared the body wall **17**, the entire apparatus **10** can be withdrawn from the wound **12** as the method of closure continues in the manner previously described.

Given the wide variations in the concept embodied in the foregoing apparatus and methods, one is cautioned not to restrict the invention to the embodiments which have been specifically disclosed and illustrated, but rather is encouraged to determine the scope of the invention only with reference to the following claims.

We claim:

1. A method for suturing a wound in a body wall having a near side and a far side, comprising the steps of:

providing a wound closure apparatus including a proximal section, a distal section and an intermediate section;

inserting the distal section through the wound from the near side to the far side of the body wall;

deploying a pair of needles through the body wall surrounding the wound to form an associated pair of needle holes;

inserting a suture having two ends and a suture loop extending therebetween directly into and through the wound from the near side to the far side of the body wall;

manipulating the suture into threading engagement with the needles;

withdrawing the threaded needles through the needle holes to access the ends of the suture on the near side of the body wall; and

withdrawing the distal section of the apparatus through the wound.

2. The method recited in claim **1**, wherein the manipulating step includes the steps of moving the suture to engage the needle on the far side of the wall to thread the needle.

3. The method recited in claim **1** further comprising the step of:

tying the ends of the suture to each other to close the wound in the body wall.

4. The method recited in claim **1** wherein the providing step includes the step of:

providing the intermediate section in the form of a rigid tube having a proximal end and a distal end; and

providing the distal section in the form of a flexible tube attached to the distal end of the rigid tube.

5. The method recited in claim **1** wherein the deploying step includes the steps of:

providing a deployment mechanism in the proximal section of the apparatus; and

operating the deployment mechanism on the near side of the body wall to deploy the needles through the body wall.

6. A method for suturing a wound formed in tissue of a body wall having a near side and a far side, the method comprising the steps of:

providing a suture having a first and a second end, and a suture loop extending therebetween;

inserting an unthreaded first needle and an unthreaded second needle through the tissue;

inserting the first end and the second end of the suture directly into and through the wound leaving the suture loop on the near side of the body wall;

manipulating the suture into threading engagement with the needles;

withdrawing the threaded needles and the associated first and second end of the suture through the tissue;

tensioning at least one of a first and second ends of the suture on the near side of the wall to draw the suture loop to the far side of the body wall; and

tying the first end to the second end of the suture to close the wound formed in the tissue of the body wall.

7. The method recited in claim **6** wherein the needles are threaded substantially simultaneously.

8. The method recited in claim **6** further comprising the steps of:

during the tensioning steps, engaging the suture loop on the near side of the body wall to tension the first and second ends of the suture on the far side of the body wall; and

during the withdrawing step, disengaging the suture loop on the near side of the body wall to draw the suture loop to the far side of the body wall.

9. A wound closure apparatus for suturing a wound in a tissue wall, comprising:

a cannula having an axis extending between a proximal end and a distal end;

a handle disposed at the proximal end of the cannula;

at least one needle disposed in proximity to the distal end of the cannula, the needle being movable between a proximal position and a distal position adjacent to the wound to be closed; and

a suture manipulator carried by the cannula and being insertable directly into and through the wound, the manipulator being operable to manipulate the suture into threading engagement with the needle when the needle is in the distal position.

10. The wound closure apparatus recited in claim **9** further comprising:

a finger tab disposed on the handle and coupled to the suture manipulator, the tab being movable relative to the handle to operate the manipulator so that the suture moves between a first position and a second position disposed radially outwardly of the first position.

11. The wound closure apparatus recited in claim **10** wherein:

the needle in the distal position is positioned generally parallel to the axis of the cannula and is disposed generally a first distance from the axis of the cannula;

the suture in the first position is positioned generally parallel to the axis of the cannula and is disposed generally a second distance from the axis of the cannula, the second distance being less than the first distance; and

the suture in the second position is positioned generally parallel to the axis of the cannula and is disposed generally a third distance from the axis of the cannula, the third distance being greater than the second distance.

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